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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,460	09/11/2003	Robert Boock	022956-0223	7148

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/661,460	Applicant(s) BOOCK ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 26-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☒ Claim(s) 1, 6, 7, 13, 15, 16, 19-21, 23 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 March 2006 is/are: a) ☒ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings were received on 03/13/2006. With the ~~--exception--~~ of Figure 7, these drawings are ~~--acceptable--~~.
2. The drawings are objected to because Figure 7 appears to be a dark color photograph. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
3. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color

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photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Objections

4. Claims 1,6,7,13,15,16,19-21,23 and 24 objected to because of the following informalities:

5. The term "substantially" in claims 1 and 13 is a relative term that appears to render the claims indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The geometry of the structure of the tissue extraction and maceration device is unclear.

6. The term "about" in claims 6,7,15,16,19-21,23 and 24 is a relative term that appears to render the claims indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claimed angles, lengths, volumes, and rotation speeds are unclear.

7. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 10-11, 21-22, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman et al (WO 99/58066).

10. For claim 1, Altman et al discloses an outer tube 14 with an open distal end, a shaft 12,55 disposed within said outer tube articulating between a first, proximal and second, distal positions exposing the distal end of the shaft from the outer tube (page 11 lines 10-22), a tissue harvesting tip 50 disposed on the distal end of said shaft, and cutting members 13,30,35 coupled to said shaft proximal to the tissue harvesting tip.

11. For claims 2-3, Altman et al discloses biasing element 65 biasing the shaft proximally and a trigger mechanism 53 connected to a shaft 12,55 that overcome said biasing elements (page 11 lines 10-22).

12. For claims 10-11, Altman et al discloses curved cutting members 30 disposed radially from the shaft (page 10 lines 4-7).

13. For claim 21, Altman discloses a motor 24, typically electric or pneumatic, coupled to the shaft and capable of rotating at speeds ranging from about 100 to 5000 rpm.

14. For claim 22, Altman discloses a harvesting tip 50 extending beyond said outer tube.

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15. For claim 25, Altman discloses a vacuum outlet 22 inducing suction in said outer tube and pulling harvested tissue therein.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 4-5 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al in view of Shapira (US 6,358,252). Altman et al discloses the claimed tissue harvesting invention 11 except for the open distal end configured to form a seal with the tissue surface or defined by an angled edge wall further comprising surface features. Shapira teaches a tissue harvesting device 10 comprising an open distal end configured to form a seal with a tissue surface and an angled edge wall including surface features, or ridges 62, as best seen in Figures 2 and 4. It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught by Altman et al, with Shapira for the purpose of increasing the suction force on the cut tissue via a seal drawing the tissue into the device and to break the tissue into smaller pieces with surface ridges on the edge wall.

19. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al in view of Thimsen et al (US 4,844,064). Altman et al discloses the claimed tissue harvesting invention 11 except for the open distal end defined by an angled edge wall wherein the angle ranges from 30-75 degrees or is about 40 degrees. Thimsen et al teaches a tissue-harvesting device 11 comprising an open distal end 16,17 with an angled edge wall equal to about 50 to about 60 degrees (column 2 lines 41-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught by Altman et al, with Thimsen et al for the purpose of increasing the cutting efficacy of the edge wall of the blade.

20. Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al in view of Lev (US 6,066,153).

21. For claims 12-13, Altman et al discloses the claimed tissue harvesting invention 11 except for the harvesting tip configured to comprise either a cone- or semi cylindrical shaped housing with a plurality of cutting disposed thereon and further configured to remove a predetermined volume of tissue. Lev teaches a tissue-harvesting device 10 with various configurations of tissue harvesting tips comprising cone-shaped members

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and a semi cylindrical-shaped members as seen in Figures 4A and 4B. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught by Altman et al, with Lev for the purpose of configuring the tissue harvesting tip for a variety of tissue removal situations.

22. For claims 14-16, Altman et al discloses the claimed tissue harvesting invention 11 except for the harvesting tip configured to harvest a predetermined volume of tissue when moved from proximal to distal positions. Lev teaches a tissue-harvesting device 10 with various configurations of tissue harvesting tips comprising dimensions inherently capable of harvesting predetermined volumes of tissue ranging from 0.5 – 1.5 cm³ (column 5 lines 37-41). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught by Altman et al, with Lev for the purpose of configuring the tissue harvesting tip for extracting a predetermined volume of tissue dependent upon the specific application.

23. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view of Majlessi (US 5,871,454). Altman et al discloses the claimed tissue harvesting invention 11 except for a sizing screen configured with openings comprising a diameter of 0.7-1.3 mm. Majlessi teaches a tissue-harvesting device 10 with permeable membrane 44" for filtering larger particulate matter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tissue harvesting device as taught by Altman et al, with Majlessi for the purpose of configuring the tissue harvesting device to filter large application specific particulates.

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24. For claims 23-24, Altman discloses the biasing element 65 biasing the shaft proximally and a trigger mechanism 53 connected to a shaft 55 that overcome said biasing elements but does not disclose expressly the biasing distance being 1 to 5 mm. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the tissue extraction device as taught by Altman to bias 1 to 5 mm, because Applicant has not disclosed that a 1 to 5 mm biasing provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the biasing element as taught by Altman, because it provides an identical function and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Altman. Therefore, it would have been an obvious matter of design choice to modify Altman to obtain the invention as specified in the claim(s).

Response to Arguments

25. Applicant's arguments filed 03/13/2006 have been fully considered but they are not persuasive. Applicant argued Altman et al does not teach or suggest disposing a shaft distally coupled with a rotor within an outer tube and configuring said shaft and rotor to move between a first proximal and second distal positions. This argument is found unpersuasive because, as broadly as structurally claimed, Altman et al discloses an outer tube 14 with an open distal end, a shaft 12,55 disposed within said outer tube articulating between a first, proximal and second, distal positions exposing the distal end of the shaft from the outer tube (page 11 lines 10-22), a tissue harvesting tip 50

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disposed on the distal end of said shaft, and cutting members 13,30,35 coupled to said shaft proximal to the tissue harvesting tip.

Conclusion

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH



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